1277761

PATENT SPECIFICATION

(11) 1277761

DRAWINGS ATTACHED

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(54) BLOOD COLLECTOR DEVICE

(71) We, MICROMEDIC SYSTEMS, INC., a Corporation organised and existing under the laws of the State of Delaware, United States of America, Rohm and Haas Building Independence Mall West, Philadelphia, Pennsylvania 19105, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to a device for collecting a percutaneous blood sample.

There are various known methods for obtaining a percutaneous blood sample, and in particular a sample from a finger.

In one of these, the area of the finger from which, blood is to be withdrawn is first disinfected and the skin is then pricked to a depth of about 2 or 3 mm. The first drop of blood issuing from the incision is removed since this contains a relatively substantial quantity of blood originating from the subcutaneous cells and the finger is then massaged in the direction of the incision. The blood obtained during this massage is collected in a test tube, in a capillary tube, or by suction into a tube.

These different stages in the taking of a blood sample are usually carried out by qualified personnel who are now becoming more and more scarce.

The apparatus of the invention allows a blood sample to be taken by the subject without the necessity of specialist attention.

Accordingly the invention provides apparatus for collecting a blood sample comprising a collection tube with a resilient collector cup at an open end, at least one lance inside the cup, directed towards its open end and such that it projects from the cup only when the cup is compressed by axial pressure, and a mass of absorbent material in the cup with the lance projecting through it.

The apparatus is particularly useful for taking a blood sample from a finger and may be used in the apparatus of our copending application No. 35716/69 (Serial No. 1277762) which enables the sample to be taken in a semi-automatic manner.

Preferred embodiments of the invention will now be particularly described, for the purposes of illustration only, with reference to the accompanying drawings in which:

Figure 1 is a sectional elevation of a first embodiment of the invention;

Figure 2 is a similar view showing the method of making an incision;

Figure 3 is a perspective view of a part of the embodiment of Figure 1;

Figure 4 is a sectional elevation of a second embodiment of the invention;

Figure 5 is a sectional elevation of a third embodiment of the invention;

Figure 6 is a view of part of the embodiment of Figure 5 after collection of a sample;

Figures 7 and 8 show partially two different constructional forms for the tube of Figure 5;

Figure 9 is a sectional elevation of a fourth embodiment of the invention; and

Figures 10 to 13 are diagrammatic sectional views, in different operating positions, of various parts of an automatic blood sampling apparatus in which devices of the invention can be used.

The device shown in Figure 1 of the drawing comprises a collection tube 1 of a transparent or translucent material, in this case polyethylene, in the mouth of which is engaged a plug 2 constituting the discharge part of a funnel 3 having a cup 4 of resilient plastics material. The cup 4 rests on the rim of the open end of the collection tube 1 by means of an annular ridge 4a on the outside of the base of the cup 4. The wall of the cup 4 and the plug 2 have an L-shaped groove 5 forming, together with the wall of the collection tube 1, a passage through which air can escape as the tube 1 is being filled with blood.

At the discharge end of plug 2 there projects a capillary tube 6 extending nearly to the bottom of the tube 1, co-axial with

the tube and forming an extension of an axial passage in the plug 2.

At the bottom of the cup 4 is an annular groove 4b which is held at the periphery of a circular plate 7 (Figures 1 and 3) of stainless steel which has two triangular stainless steel lances 8a and 8b at right angles to the plate 7, one at each end of a slot 9 in the plate.

Above the plate 7 in the cup 4 is an annular mass or pad 10 of absorbent material, in this case blotting paper, held in position by the lances 8a and 8b. As shown, the slot 9 and the opening in the pad 10 are aligned with the passage in plug 2.

The parts of the lances 8a and 8b that project above the pad 10 have a length of between 2 and 3 mm (these lances may extend further in other embodiments but not beyond the level of the upper rim of cup 4).

The lances 8a and 8b are for making the cutaneous incisions required for taking a blood sample (Figure 2) and these incisions should be sufficiently deep to reach blood vessels of some importance. One possible procedure for obtaining a blood sample will be described hereinafter with reference to Figures 10 to 13.

In the embodiment of Figure 4 the capillary tube 6a is not integral with the mouth and plug 2 of the funnel. Instead it is a separate tube forced part way into the passage 2a.

The device shown in Figure 5 differs from that shown in Figure 1, firstly in that the plug 2 of the funnel 3 does not carry a capillary tube 6, and secondly in that the air in the tubular body 1 is discharged through a capillary passage 11 axially formed in the collection tube 1. This passage 11 passes through a tubular extension 12 which is integral with the body 1 and around which is arranged a metal collar 13. Although passage 11 allows passage of air its diameter is too small to permit blood to flow through. The extension 12 is, like the tube 1, of plastics material, and can be crushed to close the passage 11 by tightening the collar 13 by crimping into the position shown in Figure 6.

Alternatively when the body 1 or at least part of the tubular element 12 is of thermoplastics material, the passage 11 can be closed off by partial fusion of the element 12 (Figure 7).

If on the other hand, the body 1 is made of a plastics or other material having a high fusion point and low elasticity, the passage 11 can be sealed by the insertion of a stopper 13A (Figure 8) of compressible material.

The embodiment of Figure 9 differs from that of Figure 1 or Figure 4, in that the lances, (14a and 14b) in cup 4 are integral with the upper end of the capillary tube 15 engaged in the passage through the plug, the lances and the tube 15 forming an integral metal piece.

The apparatus of Figures 10 to 13 comprises a casing 16 of generally rectangular section in the upper left hand part of which, as seen in Figure 10, is pivotably mounted at 17 a lever 18 having two parallel arms 18a (of which only one can be seen) connected by a common part 18b covered on one side surface with a pad of synthetic sponge 19, each arm 18a extending through a slot 16a provided in casing 16.

The free end of each arm 18a of lever 18 has ratchet teeth 20 for holding, by cooperation with pawl 21 acted by spring 22, the lever when it is swung over into the position shown in Figure 12. The spring action can be overcome by a relay 23 adapted, when energized, to rock the pawl 21 in a clockwise direction to free the lever 18. The lever is permanently biased towards the action of tending to swing it back to its raised position by a spring 24.

The lever 18 also has a beak 18c intended to cock a striker device comprising a striker 25 pivotably mounted at 26 on a lug 27 on a support 28 fixed to the base of the casing 16. The lengths of beak 18c and striker 25 and the positions of their pivotal points are such that the paths of the tip of beak 18c and the tip of lever 25 intersect one another over a defined length.

Lever 25 bears on the head 29 of a push-piece 30 biased by a spring 31 and slidable in a hole in the support 28. This push piece has, at its lower end, a stop 30a to limit its possible axial displacement in the direction of lever 25.

Above lever 25 and in the mean swinging plane of lever 18, the casing 16 has a member 32 for locating a tube co-axially with the push-piece 30 and to project from the upper face of the casing, the diameter of the cylindrical bore through this member being slightly greater than the external diameter of a collection tube of a collection apparatus (E) of the invention.

Between the member 32 and the slot 16a the casing 16 carries a fixed block 33 of trapezoidal section for aiding correct positioning of a finger from which a blood sample is to be taken on the apparatus.

On the face of the apparatus casing 16, adjacent member 32, there projects, through a slot 16b, a massaging block 34 mounted at the end of a lever 35 pivoted at 36 on a link 37 rigid with a shaft 38 which by means of a motor (not shown) can be rotated in an anti-clockwise direction when viewed as in Figure 10. As shown in Figure 11, the position of the block 34 on the casing is such that when the subject from whom a blood sample is to be taken places one of his finger tips against block 33 and lever 18 has been swung down, the pad 19 of lever 18

bears against the part of the finger placed on block 34.

When a blood sample is about to be taken, the various parts of the apparatus occupy the positions shown in Figure 10.

A blood collector device E is then placed within the bore in member 32 so that its funnel cup is flush with the upper opening of said member.

The subject then lays his hand on the upper face of casing 16 and places the finger to be bled on the massage block 34 with the tip of the finger against the locating block 33 in such a way that the distal part of the finger underlying the nail rests on the rim of the funnel member, as shown in Figure 11. The area of the finger where the incisions are to be made should have been previously cleaned and disinfected.

To take the sample, lever 18 is swung downwards to bring it into the locked position shown in Figures 12 and 13. The necessary incisions are made in the epidermis of the finger because the movements of lever 18 cause beak 18c to bear on lever 25, thereby depressing the latter to compress spring 31, this cooperation between beak 18c and lever 25 continuing as long as the curvilinear paths of their tips intersect one another (Figure 11).

When these two paths cease to intersect, lever 25 is freed from engagement with beak 18c and then is subjected to the freed action of the compressed spring 31 which pushes it abruptly against the base of the collection tube of device E (Figure 12).

This tube is then pushed in the direction of the finger, causing it to slide within the bore in member 32 and to deform the cup 4 of the funnel member 3 (Figure 2) on which the finger tip bears, and hence to drive the lances 8a and 8b into the finger to produce the required incisions of the epidermis and dermis.

As soon as the kinetic energy communicated to the tubular body of the blood collector device by percussion has been dissipated, partly by deformation of cup 4 and partly by the formation of the incision, the blood collector tube is urged back to the lowered position shown in Figure 13 under the action of the cup 4 which acts as a resilient return member whilst resuming its original shape. As the tips of the lances extend at most to the level of the rim of cup 4 when the latter is not deformed, the lances will be completely withdrawn from the incisions they have made when the cup resumes its undeformed position so that it is then possible to proceed to collect a blood sample without the subject, feeling any impediment or pain.

To obtain a blood sample, shaft 38 is set in rotation and this imparts an eccentric movement to lever 35 and consequently an undulatory movement to the massage block 34, alternately towards the stationary block 33, during an ascending phase, and in the opposite direction, during a descending phase (Figure 13).

As the finger of the subject is gripped between the pad 19 and the block 34, this undulation of the block 34 cyclically compress the underside of the finger from the rear towards the front thereby massaging the digital tissue and promoting a periodic flow of blood towards the incisions.

The blood issuing from these incisions flows first into cup 4 (Figure 1) and then through cannula 6 into the collection tube 1, the air in this body escaping through groove 5 as filling proceeds (or in the embodiments of Figures 5 and 8, through passage 11).

It is to be noted that the first few drops of blood entering the cup are not collected in the collection tube 1 but are absorbed by the absorbent pad 10. This is advantageous because these drops of blood contain a very high proportion of physiological liquid which originates from the sub-cutaneous cells and which is undesirable in a blood sample.

Thus it is only when the pad 10 has been sufficiently impregnated with a mixture of physiological liquid and blood, that the blood issuing from the finger will be more suitable for sampling and it is this blood that will flow into the collection tube 1. In this connection it is to be noted that the lances considerably facilitate this flow because, although removed from the epidermis they lie directly opposite the incisions and are at a very short distance from them so that the drops of blood issuing from the incisions fall on and are ruptured by the tips of the lances and then flow rapidly over the surface of the latter into the tube 6. The lances thus effectively play the part of collectors, preventing the formation of a thick blood dispersion in the cup 4.

The massage performed by the movement of the block 34 is, of course, stopped when the blood in the tubular body 1 reaches a desired level.

At that point the relay 23 is energized to release lever 18 which then frees the finger. The filled blood collector apparatus E is then manually removed from the tubular member 32, whereupon the funnel member 3 and associated cannula 6 may be removed from the tubular body 1. The latter is then closed by a suitable stopper in order to prevent coagulation of the blood collected, in particular when it is not to be subjected to an immediate examination. At this time also, in the case of the embodiments of Figures 5 and 8, the air release passage 11 is sealed as above described.

WHAT WE CLAIM IS:—

1. Apparatus for collecting a blood sample comprising a collection tube with a resilient collector cup at an open end, at least one lance inside the cup, directed towards the open end of the cup and such that it projects from the cup only when the cup is compressed by axial pressure, and a mass of absorbent material in the cup with the lance projecting through it.

2. Apparatus as claimed in Claim 1 in which the cup is the cup of a funnel and the narrower end of the funnel comprises a capillary tube extending into the collection tube.

3. Apparatus as claimed in Claim 2 in which the capillary tube is detachable from the funnel cup and the lance is integral with the capillary tube.

4. Apparatus as claimed in Claim 1 or 2 in which the lance is integral with a base plate located in or near the point of the collector cup.

5. Apparatus as claimed in any of Claims 2 to 4 wherein an outlet for air displaced by blood entering the tube is provided by an aperture between the tube open end and the funnel when the latter is inserted into it.

6. Apparatus as claimed in any of Claims 1 to 4 wherein an outlet for air displaced by blood entering the tube is provided by a capillary outlet from the tube of such diameter as to allow air but not blood to flow from the tube.

7. Apparatus as claimed in Claim 6 wherein means are provided for closing the capillary outlet from the collection tube.

8. Apparatus as claimed in any preceding Claim for collecting a blood sample from a finger.

9. Apparatus for collecting a blood sample substantially as described in any of Figures 1 to 9 of the accompanying drawings.

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3 SHEETS *This drawing is a reproduction of the Original on a reduced scale*

Sheet 1

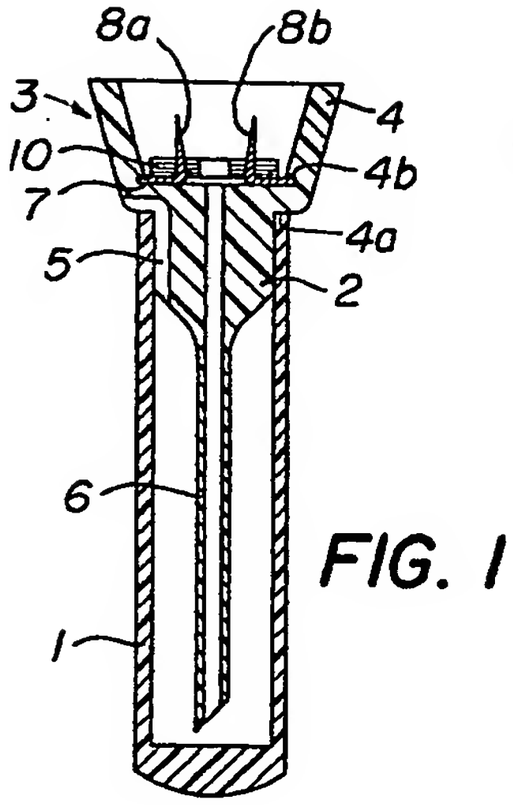

FIG. 1

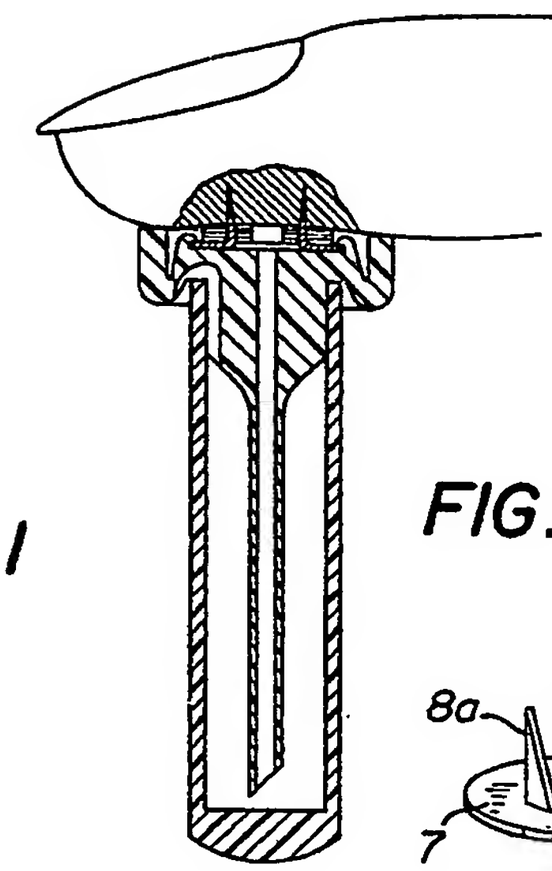

FIG. 2

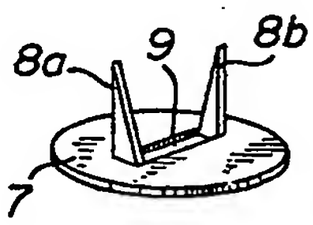

FIG. 3

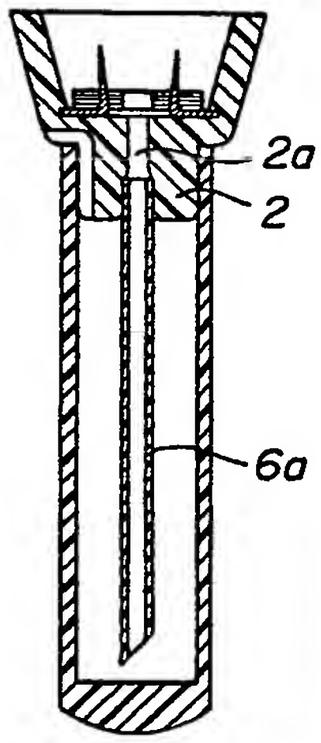

FIG. 4

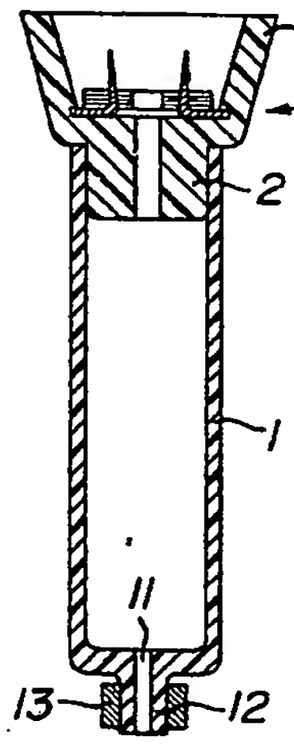

FIG. 5

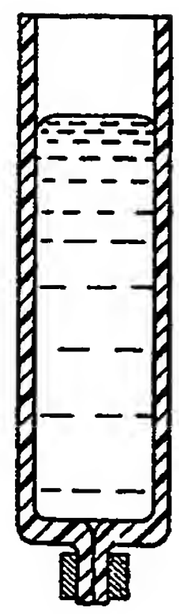

FIG. 6

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FIG. 7

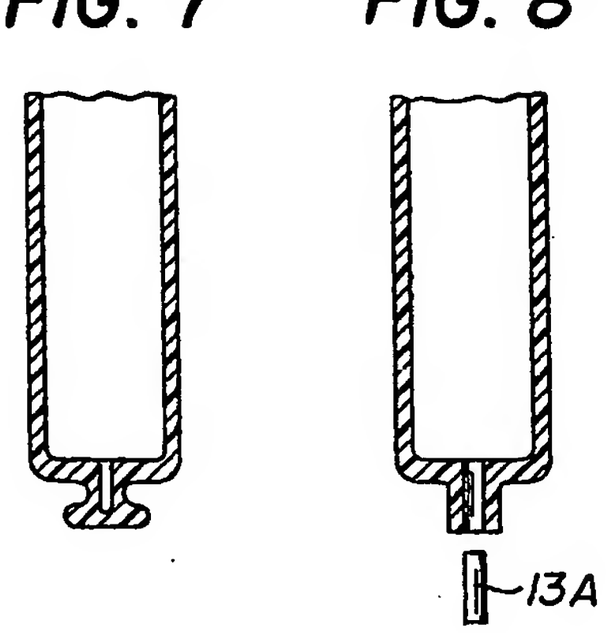


FIG. 8

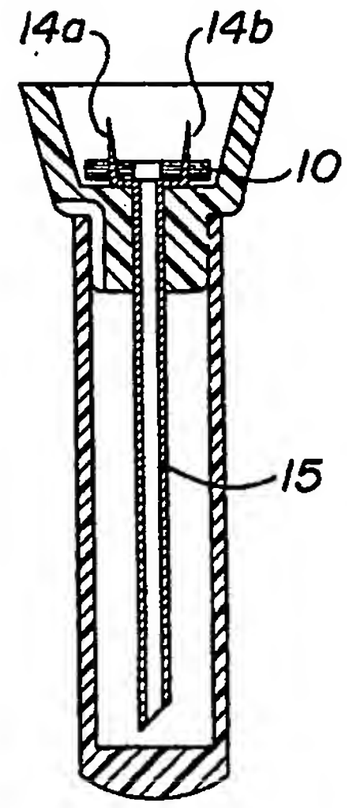


FIG. 9

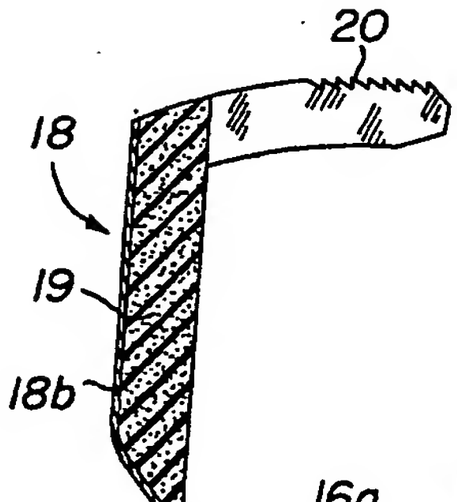
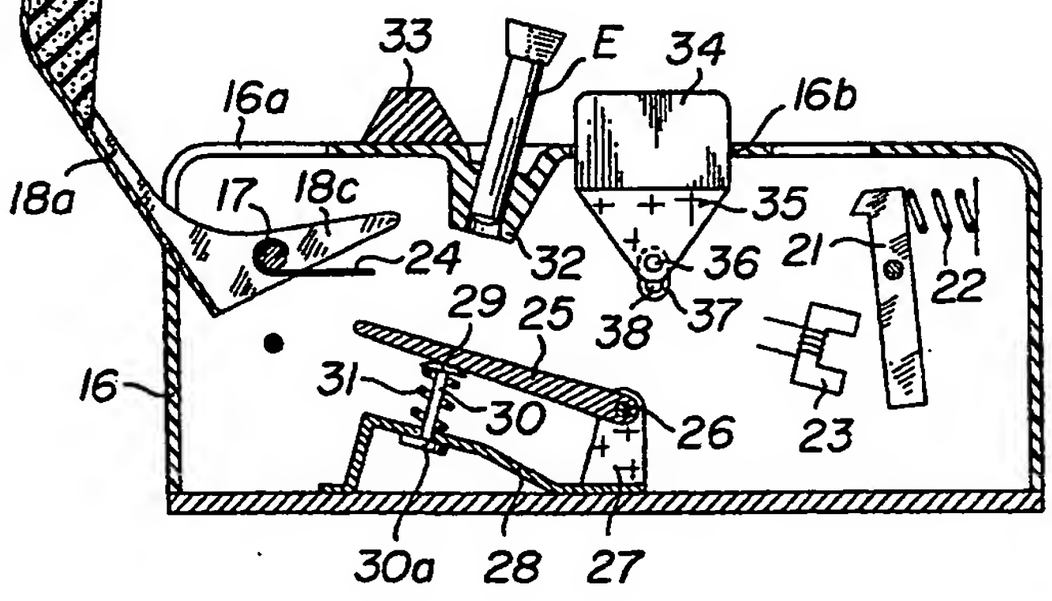


FIG. 10



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Sheet 3

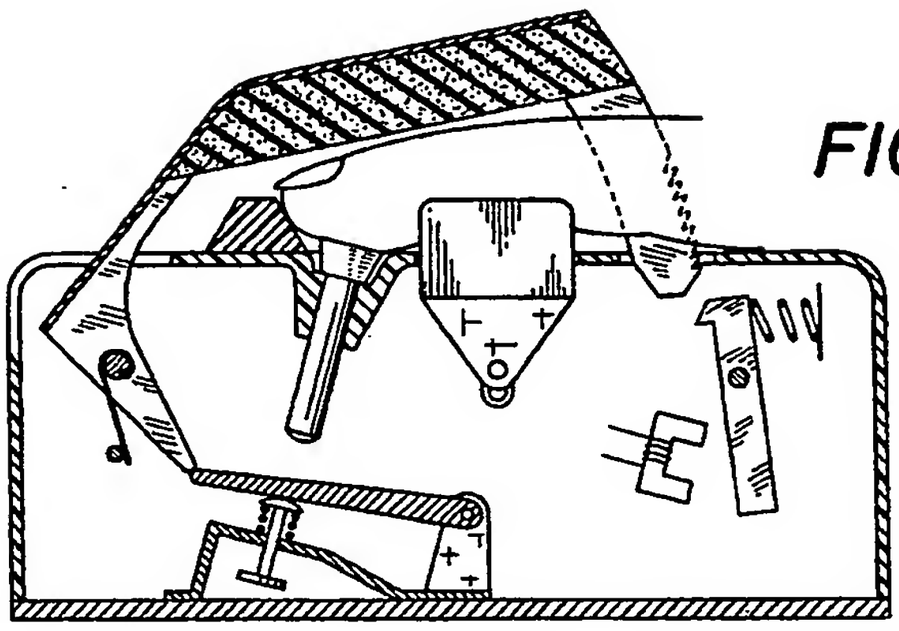

FIG. 11

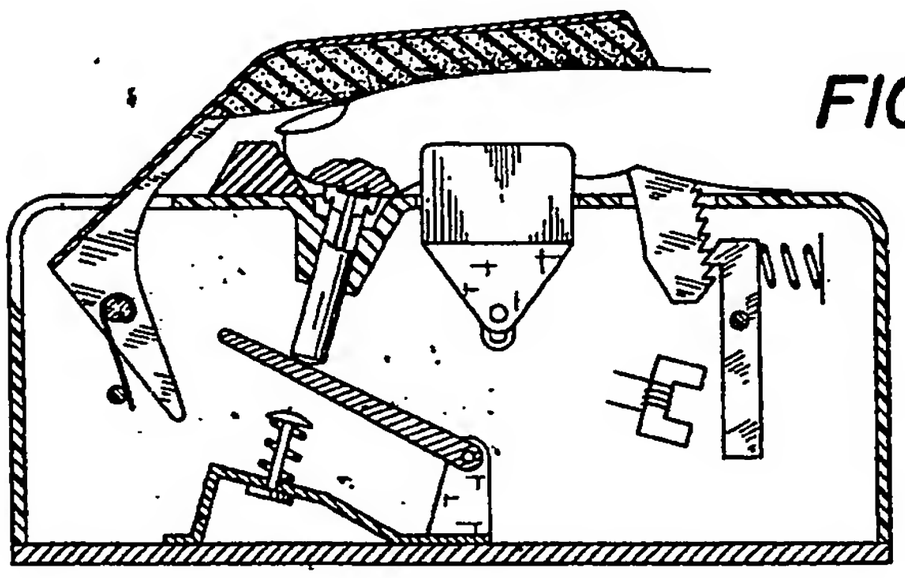

FIG. 12

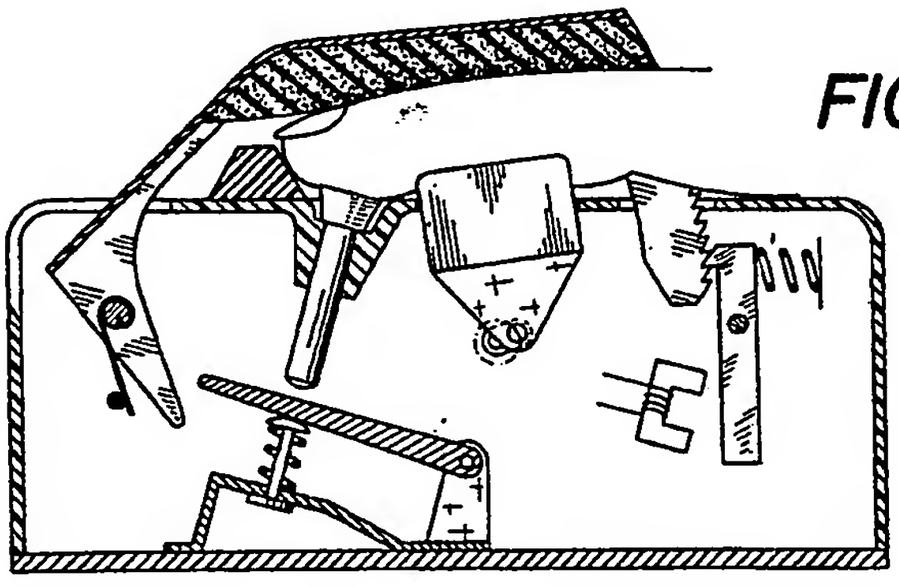

FIG. 13